



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

February 15, 2005

**FILE COPY**

John R. Manthei  
Latham & Watkins LLP  
555 Eleventh Street, N.W., Suite 1000  
Washington, DC 20004-1304

Dear Mr. Manthei:

Your petition, on behalf of Bone Medical Limited, requesting the Food and Drug Administration declare that Oral Salmon Calcitonin is suitable for submission as an Abbreviated New Drug Application, was received by this office on 02/14/2005. It was assigned docket number 2005P-0070/CP1 and it was filed on 02/15/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2005P-0070

ACK